DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Registration and Listing Grassroots Meeting for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Registration and Listing Grassroots Meeting for Medical Device Manufacturers. The topic to be discussed is FDA's intention to propose changes to the current medical device registration and listing process. This meeting is being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes manufacturers to register their establishments and list their devices, while ultimately reducing FDA's cost of maintaining the registration and listing system.

DATES: The meeting will be held on May 25, 1999, 8:30 a.m. to 12 noon; registration will begin at 7:30 a.m.

ADDRESSES: The meeting will be held at 9200 Corporate Blvd., rm. 20B, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Bryan H. Benesch, Food and Drug Administration, Center for Devices and Radiological Health, Office of Health and Industry Programs (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 ext. 131, (FAX) 301–443–8810, (e-mail) ''BHB@CDRH.FDA.GOV''.

Those persons interested in attending the meeting should fax or e-mail their registration including name, title, firm name, address, telephone, and fax number. There is no charge to attend this meeting, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Bryan H. Benesch at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Over the past one and a half years, FDA has reviewed the entire registration and listing process to determine if the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of suggestions aimed at improving the registration and listing process for both FDA and industry. This meeting will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes. FDA has announced two meetings on the same subject to be held April 20, 1999, in California (64 FR 12813, March 15, 1999).

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the World Wide Web (WEB). What are the advantages and disadvantages to industry, and how would industry be affected if WEB submissions were mandated?

(2) Require that owners and parent companies register, list, and take responsibility for the registration and listing of their establishments. What is the highest level in a company that should be responsible for registration and listing, and how should this level be defined/described?

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), premarket approval, or product development protocol process.

(4) Because of the ease of submission through the WEB, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of the meeting will be available on CDRH's website approximately 15 working days after the meeting. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

Dated: April 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0693]

''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test.'' The guidance document is intended to provide guidance to applicants on the content and format of the chemistry, manufacturing and controls (CMC) and establishment description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' (revised Form FDA 356h) for an allergenic extract or allergen patch test. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at